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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/362,598 07/28/99 WEINSTOCK

J 3948/79934

HM12/1213

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EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

4

DATE MAILED:

12/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/362,598

Applicant(s)

Weinstock et al

Examiner

Li Lee

Group Art Unit

1645

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-32 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-32 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1645

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 22-23, drawn to a method of treating an excessive immune response by administering a helminthic parasite preparation, classified in class 514, subclass 12.
 - II. Claims 13 and 14, drawn to a method of treating inflammatory bowel disease by administering a helminthic parasite preparation, classified in class 514, subclass 12.
 - III. Claims 15 and 16, drawn to a method of vaccinating by administering a helminthic parasite preparation, classified in class 514, subclass 12.
 - IV. Claims 17 and 18, drawn to a composition of helminthic parasite preparation, classified in class 530, subclass 350.
 - V. Claims 19 and 20, drawn to a method of producing helminthic parasite preparation, classified in class 435, subclass 71.1.
 - VI. Claim 21, drawn to a method of treating a disease involving inflammatory cells in CNS administering a helminthic parasite preparation, classified in class 514, subclass 12.
 - VII. Claims 24-32, drawn to a method of screening a helminthic parasite preparation, classified in class 435, subclass 7.1.

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2. The inventions are distinct, each from the other because of the following reasons:

Groups I-III and V-VII are drawn to independent and distinct methods. They differ in the method objectives (e.g., treating an excessive immune response, treating inflammatory bowel disease, vaccinating an individual against an excessive immune response, treating a disease involving inflammatory cells in CNS, or screening a helminthic parasite preparation), protocols (e.g., treatment protocol reduction of an immune response versus vaccination protocol induction of an immune response), and have different final outcomes.

Inventions Group IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of producing a helminthic parasite preparation can be used to produce materially different helminthic parasite purified antigens from a mammal housed in a non-pathogen free environment other than that from a mammal housed in a specific pathogen-free environment.

Inventions Group IV and Groups (I-III and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the helminthic parasite preparation of Group IV can be used in materially different methods such as generating antibodies or in vitro assays.

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Inventions IV and VII are independent and distinct, wherein the composition of helminthic parasite preparation of Invention IV can be neither made nor used in the method of Invention VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by the different classification, and absent restriction would place an undue search and examination burden on the examiner, therefore restriction for examination purposes as indicated is proper.

3. A telephone call was made to Kathleen Williams on 11/10/99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee, M.D., Ph.D. whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995.

Li Lee, M.D., Ph.D.
December 6, 1999



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600